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March 23, 2009

Docket No. DEA-316

Drug Enforcement Agency

Attention: DEA Federal Register Representative/ODL

8701 Morrisette Drive

Springfield, VA 22152

Via E-mail: dea.diversion.policy@usdoj.gov

Dear Sir or Madam:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the Drug Enforcement Agency's (DEA) Advance Notice of Proposed Rulemaking (ANPRM) (January 21, 2009; 74 *Fed. Reg.* 3480) seeking information on the disposal of controlled substances. NACWA and its nearly 300 public wastewater treatment utility members understand the potential impacts of unused pharmaceuticals that are mishandled or inappropriately disposed. Recent press coverage and Congressional interest in the quantities of pharmaceuticals being detected in the Nation's waters is focusing attention on the need for proper handling and disposal of pharmaceuticals by health care professionals and the general public. NACWA is interested in finding a management framework that will keep unused pharmaceuticals from entering the water environment, ensure that controlled substances are responsibly handled, and minimize the burden on limited local resources.

In many communities across the country, citizens and health care professionals are receiving mixed messages about the disposal of unused pharmaceuticals. Guidance from the federal government, including the Office of National Drug Control Policy (ONDCP), outdated prescription inserts and management policies, community-level outreach and a long list of other sources have been providing a range of directions for handling unused pharmaceuticals, from flushing to disposal in household trash to using take-back/collection programs. A 2007 policy statement from the ONDCP, in partnership with the Department of Health and Human Services (HHS) and the U.S. Environmental Protection Agency (EPA), attempted to provide coordinated federal guidelines on the handling of unused pharmaceuticals, but succeeded only in causing more confusion when it initially included a list of drugs that should be discarded via flushing to the sewer system.

NACWA members and their counterparts in the drinking water community continue to face growing pressure from their ratepayers, the press, Congress, and EPA to address the issue of pharmaceuticals in water. Take-back programs for unused pharmaceuticals are one of the few tools utilities currently have to address the issue. Building on their experience running household hazardous waste collection programs, many communities have held successful pharmaceutical collection (or take-back) events, keeping thousands of pounds of pharmaceuticals out of the sewers and raising the level of awareness in their communities regarding the impacts of what they flush down the toilet. The handling of controlled substances, however, has presented a major obstacle for these events. The current system, that requires a law enforcement official to be present and accept any controlled substances that may be brought to the event, requires utilities to arrange for and pay for the officer's time and usually requires the presence of a pharmacist or other medical professional to help identify and segregate the controlled substances. Some collection events are limited to non-controlled substances to avoid these issues, but those present challenges as well in discerning what can and cannot be accepted.

National Framework Needed for Managing Unused Pharmaceuticals

The DEA's ANPRM seeks input on a list of questions geared toward those clean water agencies that have experience with take-back programs and the problems presented when determining how best to handle controlled substances. Several NACWA members and other clean water agencies will be providing the Agency with input on how their local efforts could be aided by changes in the requirements for managing controlled substances. However, NACWA believes that more is necessary than small targeted changes to controlled substances management requirements. The current patchwork of take-back programs would benefit from more flexibility in the handling of controlled substances, and such flexibility might encourage the development of other programs. But nationwide, the vast majority of communities will not have the resources to establish and/or maintain these programs for the long-term. NACWA believes that a national framework for how these wastes can be safely and responsibly managed is needed. Such a framework will require a more coordinated approach from the federal agencies responsible for the management of the pharmaceuticals throughout their entire life cycle.

A national dialogue has been initiated on the issue of managing unused pharmaceuticals by the Product Stewardship Institute (PSI). The first two meetings of the dialogue have provided unparalleled opportunities to discuss the issues and enabled a very open discussion among the various federal, state, local, and private interests involved. While the dialogue is exploring a range of possible solutions, NACWA believes the product stewardship model takes the appropriate approach. It seeks to have all participants involved in the life cycle of a product take shared responsibility for the impacts to human health and the environment that result from the production, use, and end-of-life management of the product. This presents some promising options for dealing with the issue of unused pharmaceuticals on a national scale. NACWA is supporting the PSI in its efforts to maintain a dialogue on national solutions to the issue.

While local efforts to establish collection programs have been effective, they are limited in reach and pose a significant resource burden for the utility. A national framework could provide more access to take-back programs for all communities and reduce the burden of developing programs city by city or town by town.

Such a national approach would also provide greater certainty in the handling of controlled substances, as it would eliminate the current patchwork of programs.

Challenges Remain for a National Program

Using a product stewardship approach, pharmaceutical manufacturers would bear the largest share of the responsibility for ensuring that unused pharmaceuticals are handled properly. An attempt to mandate pharmaceutical manufacturers to pay for collection programs in one state was not successful. But key representatives of the pharmaceutical industry are participating in the PSI dialogue and are very interested in being part of a national solution. Arguments have been made that the quantity of pharmaceuticals that would be kept out of the sewer system and the Nation's waters through a nationally coordinated take-back program is small, but currently this is the only controllable source of pharmaceuticals entering the environment. NACWA members and their counterparts in the drinking water community continue to face growing pressure from their ratepayers, the press, the U.S. Congress, and EPA to address the issue of pharmaceuticals in water. A national framework for take-back programs would provide a more coordinated approach that would minimize the diversion potential for controlled substances, reduce the burden on utilities, and address a major controllable source of pharmaceuticals in the Nation's waters.

NACWA also believes that more effort is needed to improve prescription-dispensing practices nationwide. The DEA has implemented some programs to minimize pharmaceutical waste, but a more concerted national effort could help reduce the overall quantity of pharmaceuticals that go unused. Minimizing the amount of unnecessary medications will greatly reduce the costs associated with their disposal and destruction.

NACWA appreciate the opportunity to comment on the ANPRM. Please contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hornback", written in a cursive style.

Chris Hornback
Senior Director, Regulatory Affairs